AMENDMENTS TO THE CLAIMS:

The following is a complete listing of the claims presently in the application, wherein claims 1, 5, 9, 14-21, 23, 24, 32, 36-38, 40-46, 52-56, 58-60, 63-65, 68-70, 75, 77, 81-83, 91-94, 96, 97, 100, and 101 are amended and claims 7, 8, 12, 13, 22, 39, 49, and 57 are canceled and new claims 102-103 are added:

1. (currently amended) An apparatus for providing therapy to a patient having, or who may potentially develop, a neurodegenerative disease characterized by abnormal proteins or prions or related deposits comprising:

(a) at least one emitter ~~means~~ to deliver acoustic, ultrasonic or vibratory energy in, into, through, toward, from within or coupled-into a region of the patient's brain or spine which contains, or is in transportable communication with, cerebrospinal fluid (CSF) or blood capable of bearing or bearing a chemical or biological species, reactant, fragment, by-product or species related to the disease;

(b) ~~the~~ said at least one emitter operable to at least one of: (1) enhance, promote or enable, directly or indirectly, the formation and/or transport of the species, reactant, fragment or byproduct which is at least ultimately transportable out of a brain or spine region and into a CSF space, lumen, cavity or bloodstream, (2) enhance the transport or mixing of the species within CSF and/or blood or across tissues or existing barriers and membranes, and (3) enhance or promote the increased production of fresh CSF or blood;

(c) said at least one of enhanced formation, transport, mixing or production contributing at least ultimately to some removal of said species from the body and/or at least some immediate or later reduction in concentration of said species in a portion of the body at least in part by using one or more natural paths, emitter-enhanced paths, drug-enhanced paths, surgical or artificial ~~shunting means~~ shunts, ports ~~means~~, or internal or external dialysis or ~~filtering means~~ filters, thereby at least slowing or stopping a disease process; ~~and~~

(d) said at least one emitter incorporating, is thermally coupled to, or is thermally managed or monitored by a cooling device, temperature control device or temperature monitoring device which controls or monitors the temperature of at least one of (a) at least one emitter, (b) any portion of a patient's anatomy, (c) the temperature or flow of a coolant, and (d) the temperature of an acoustic couplant material juxtaposed to an emitter; and

(e) said patient optionally receiving a ~~drug~~ substance before, during or after an operation of the emitter(s) to at least one of: (1) act or help act against a disease process or a contributing factor thereto, (2) promote the formation or transport of a species that is to be removed or is more easily removable than a natural species, (3) encourage or enable growth or regrowth of new or transplanted brain or stem cells or enhance functional brain or neural pathways, (4) encourage or enable the beneficial uptake, processing or interaction of a genetic medicament, and (5) minimize potential or expected side-effects of an emitter exposure or shunting or port procedure., at least one such ~~drug~~ substance acting at least one of independently of, in cooperation with, or synergistically with an acoustic exposure.

2. (original) The apparatus of claim 1 wherein the apparatus accelerates or enables diffusional, perfusive or other mass-transport of species across a brain/CSF interface, brain/blood interface, CSF/blood interface, membrane, interface or blood-brain-barrier in any direction.

3. (original) The apparatus of claim 1 wherein the apparatus accelerates diffusional, perfusive or mass-transport of species or of CSF or of any CSF-contained species across the arachnoid villi or arachnoid membrane in any direction.

4. (original) The apparatus of claim 1 wherein the apparatus provides acoustically driven stirring, streaming, perfusion or flow of blood in a blood flowpath/lumen or of CSF in a CSF cavity or lumen, the enhanced or initiated flow contributing to mass transport of a species in a direction useful for its natural or artificial removal from the body.

5. (currently amended) The apparatus of claim 1 wherein the apparatus operates in cooperation with or in support of a shunt, a port, a ~~filtration or~~ dialysis ~~means~~ filter, or ~~any means~~ other device used to controllably extract or cleanse CSF or blood of a species having relevance to a neurodegenerative disease process.

6. (original) The apparatus of claim 1 wherein the apparatus operates in at least one of the following manners:

(a) it provides or encourages, at least in part, at least some increased production of fresh or new CSF;

(b) it allows for the use of a port rather than a shunt;

(c) it allows for the shorter-period deployment of a shunt or port or the entire avoidance thereof;

(d) it allows for a shunt or port to remove CSF or undesired species more quickly or more safely such as at a lower flow rate or at a more benign pressure;

(e) it enhances the body's own removal rate for an undesired species at least temporarily;

(f) it allows for the avoidance of the use of at least one of a shunt or port;

(g) it provides ultrasound-assisted drug therapy supportive of the slowing or stopping of a neurodegenerative disease;

(h) it treats Alzheimer's Disease or factors thought to lead thereto;

(i) it increases transport of an undesired species or a species involved in a neurodegenerative disease process into the bloodstream or into CSF; and

(j) it interferes with a disease pathway, whether physical, chemical, biological or genetic.

7. (canceled)

8. (canceled)

9. (currently amended) The apparatus of claim [[8]] 1 wherein ~~therapeutic~~ acoustic, ultrasonic or vibratory energy is directed or passed through or across at least a portion of the patient's blood-brain barrier, arachnoid-villi, arachnoid membrane or skull bone.

10. (original) The apparatus of claim 9 wherein at least some of said therapeutic acoustic or vibratory energy opens at least a portion of said blood-brain barrier, arachnoid-villi or arachnoid membrane, at least temporarily, for enhanced passage at least one of inwards or outwards, of medicaments, drugs, byproducts of the deposition therapy process itself or of a disease species.

11. (original) The apparatus of claim 9 wherein said therapeutic acoustic or vibratory energy is at least one of: (a) below the unaided cavitation threshold and therefore blood brain barrier opening via unaided cavitation mechanisms is largely avoided, (b) above the unaided cavitation threshold and therefore cavitation significantly aids the opening of the blood brain barrier, (c) above a reduced energy level required to cavitate or excite an administered microbubble, microparticulate or other cavitation or excitation agent such that its vibrational motions significantly aids opening of the blood brain barrier, and (d) sufficient to enable or enhance transport of blood or a disease species across the arachnoid villi.

12. (canceled)

13. (canceled)

14. (currently amended) The apparatus of claim [[13]] 1 wherein said at least one emitter is located in a natural neurological lumen, cavity or passage adjacent to or within the brain or neurological system and said emitter is capable of emitting or directing therapeutic energy into a surrounding, adjacent or nearby brain or neurological region.

15. (currently amended) The apparatus of claim [[13]] 1 wherein said at least one emitter is located in or delivered into said skull via access through a craniotomy, other skull borehole or opening, via any natural body lumen, through the vascular system or through a natural interior space or cavity.

16. (currently amended) The apparatus of claim 1 wherein said at least one emitter ~~is operated~~ has at least one operating characteristic that operates at least a portion of the time, wherein said ~~with~~ at least one operating characteristic is selected from the group consisting of continuous wave operation (CW), pulsed wave operation (PW), single-pulse operation, shaped-pulse operation, multipulse operation, pulse-train operation, broadband operation, narrowband operation, chirped operation, multitone operation, multifrequency operation, having a harmonic frequency, having a pre-determined waveform, having controlled duty-cycle operation, having a predetermined frequency component or spectrum, having a fundamental or primary frequency, having a variable frequency, having a predetermined constant or variable

amplitude, emitting a compressive and/or rarefaction wave, emitting a shear wave, or having a frequency useful for manipulating a microbubble, microparticle or contrast agent.

17. (currently amended) The apparatus of claim 16 wherein output from said at least one emitter is at least one of focused, collimated, weakly focused, unfocused, diffused, diffuse, defocused, beamformed, steered or wiggled in any manner.

18. (currently amended) The apparatus of claim 17 wherein formation of said output from said at least one emitter employs electronic phase-delays applied across subelements within one or more individual emitters or across different emitters such electronic beam-steering or beam-forming takes place.

19. (currently amended) The apparatus of claim 17 wherein formation of said output from said at least one emitter employs mechanical shaping of an acoustic component of one or more individual emitters such that at least one said emitter utilizes a mechanically-shaped acoustic component for shaping acoustic emission from at least that emitter.

20. (currently amended) The apparatus of claim 1 wherein ~~multiple acoustic or vibration emitters are employed~~ a plurality of said emitters is employed, at least some of said emitters temporally capable of at least one of individual, simultaneous, sequential, interleaved, overlapping, and phase-delayed operation relative to at least one other emitter.

21. (currently amended) The apparatus of claim 20 wherein at least some of said emitters are arranged in at least one of the following manners:

(a) at least one of said emitters is one of mechanically defocused, mechanically collimated, mechanically weakly focused, mechanically focused, or mechanically diffused or diffuse and said ~~multiple~~ plurality of emitters together allow for greater total brain-volume coverage or skull-area coverage than that offered by a single said emitter;

(b) the arrangement of (a) but wherein electronic phase-delay firing between at least two said emitters is also used for purposes of beam forming, steering, slewing or wiggling of emissions;

(c) the arrangement of (a) or (b) wherein phase delays are applied within at least one said emitter possessing at least two subelements such that at least one said emitter can internally provide some beam manipulation or slewing;

(d) at least one said emitter is mounted in or to a receptacle, hole or locating mechanism in or on a headpiece designed to hold or position at least one emitter;

(e) at least one said emitter can be attached to, mounted upon or located by said patient's headpiece in more than one possible position or angle relative to the skull;

(f) at least one said emitter is mounted in, on or located by said patient's head-piece in response to known brain or neural therapy target positions as determined by a brain or neural image;

(g) at least one said emitter is acoustically coupled into a patient's brain or neurological region, with or without the aid of a headpiece or other emitter housing or ~~locating means~~ locator; and

(h) at least one said emitter is acoustically coupled into the skull or a therapy target region using an intermediate acoustically conductive film, gel, paste, cream or liquid.

22. (canceled)

23. (currently amended) The apparatus of claim [[22]] 1 wherein at least one temperature of at least one portion of said patient's anatomy is monitored, deduced or projected and utilized in controlling, limiting, adjusting or setting a power delivery parameter of said system, manually or automatically.

24. (currently amended) The apparatus of claim 1 wherein said at least one emitter is ~~located inside the patient's skull, the emitter~~ capable of emitting acoustic or vibration therapy energy into at least one selected adjacent or affected brain or neurological region, said at least one emitter being at least one of: (a) an emitter which emits a fixed beam relative to itself, (b) an emitter which emits an electronically steerable beam, steerable relative to itself, (c) an emitter which can have its beam mechanically steered or moved via physical movement of the emitter itself or of an interior portion thereof, and (d) an emitter which emits a focused, weakly focused, collimated, defocused, unfocused diffused or diffuse emission pattern.

25. (original) The apparatus of claim 1 wherein the system is sufficiently portable that it may be operated in at least one of: (a) at a patient's home, (b) at a clinic, (c) at a nursing home, (d) at a doctor's office, (e) at an out-patient facility, (f) next to a chair or bed in which the patient resides, (g) at a chosen hospital bedside, and (h) in a manner allowing the patient to view or hear music, television or video content and thus be simultaneously entertained.

26. (original) The apparatus of claim 1 wherein at least one brain or neurological region is chosen for a therapy exposure or session, or such an exposure or session is designed, planned or monitored with the help of at least one of the following:

(a) at least one radiological, diagnostic or functional image or graphic representation of said patient's brain, brain function, metabolism, neurology or neurological function or disease state;

(b) at least one statistical model or database based on a relevant patient or human population;

(c) at least one lab-test or clinical test performed on said patient or on at least one patient's lab specimen, invasively or noninvasively; and

(d) at least one incidence of at least one of the above choosing, designing or monitoring methods taking place at least once before, during or after a therapy.

27. (original) The apparatus of claim 26 wherein said image or graphical representation is obtained using at least one of: positron-emission tomography (PET), single photon emission computed tomography (SPECT), functional positron emission tomography (fPET), magnetic resonance imaging (MRI), functional magnetic resonance imaging (fMRI), computed tomography (CT), computer aided tomography (CAT), X-Ray imaging, fluoroscopy, and ultrasound imaging (US) or using a spectroscopy technique based on one or more of these tools.

28. (original) The apparatus of claim 26 wherein said statistical model or database is one based on at least one of: (a) a database including living or deceased patients, (b) a database including genetic tendencies to acquire said disease or of genetic test results, (c) a database including risk factors for said disease, (d) a database including lab-test or clinical-test re-

sults, (e) a database including data from said patient, (f) one or more radiological, diagnostic or functional image of at least one patient, and (g) any patient record or report.

29. (original) The apparatus of claim 1 wherein a parameter of a given therapy session or a number of or parameter of further sessions to be undergone is determined, at least in part, by the use of at least one lab-test or by a radiological, diagnostic or functional image or graphical representation which provides information relating to the current state, a recent state or an anticipated state of said disease in said patient.

30. (original) The apparatus of claim 29 wherein at least one said lab-test involves the taking or observing of a sample or portion of bodily fluid or bodily tissue and said sample is either non-invasively observed or is physically taken from the patient at least once, at least temporarily, before, during or after a therapy.

31. (original) The apparatus of claim 29 wherein at least one said lab-test involves the observation, recording or measurement of a property or state of the patient's spinal fluid, blood, urine, skin, tissues, other bodily fluid or physiological parameter and said lab-test is performed on said patient or on patient's sample at least once before, during or after a therapy invasively or noninvasively.

32. (currently amended) The apparatus of claim 1 wherein an abnormal protein-related or prion-related disease affecting or expected to potentially affect the patient's brain or neurological system, directly or indirectly, is ~~diagnosed to possibly, likely or certainly be one or more of~~ at least one of: Guam-Parkinsonism dementia complex, Dementia Pugilistica, Parkinson's Disease, adult Down Syndrome, Subacute Sclerosing Panencephalitis, Pick's Disease, Corticobasal Degeneration, Progressive Supranuclear Palsy, Amyotrophic Lateral Sclerosis/Parkinsonism Dementia Complex, Hallervorden-Spatz Disease, Neurovisceral Lipid Storage Disease, Mediterranean Fever, Muckle-Wells Syndrome, Idiopathetic Myeloma, Amyloid Polyneuropathy, Amyloid Cardiomyopathy, Systemic Senile Amyloidosis, Hereditary Cerebral Hemorrhage with Amyloidosis, Alzheimer's Disease, Scrapie, Creutzfeldt-Jacob Disease, Fatal Familial Insomnia, Kuru, Gerstamnn-Straussler-Scheinker Syndrome, Medullary Carcinoma of the Thyroid, Isolated Atrial Amyloid, Beta2-Microglobulin, Amyloid in dialy-

sis patients, Inclusion Body Myositis, Beta2-Amyloid deposits in muscle wasting disease, Islets of Langerhans Diabetes Type2 Insulinoma or the Polyglutamine diseases including Huntington's Disease, Kennedy's Disease, and all forms of Spinocerebellar Ataxia involving extended polyglutamine tracts.

33. (original) The apparatus of claim 32 wherein the disease is a form of Alzheimer's Disease and at least one type of or quantity of undesired plaque or deposit is being formed or is expected to form.

34. (original) The apparatus of claim 33 wherein a targeted plaque or plaque-forming process is related to at least one of senile plaque and fibril plaque formation contributing to a current or anticipated form of Alzheimer's disease.

35. (original) The apparatus of claim 1 wherein said substance comprises at least one of a drug, medicament, vitamin, mineral or controlled dietary matter or content is either (a) utilized in support of or in cooperation with at least one plaque or prion related breakup-process, formation-interference process, or disease recovery process such that the total overall therapy delivered over one or more therapy sessions incorporates the use of said drug, medicament, vitamin, mineral or dietary matter or content and the use of said acoustic or vibratory exposure therapy, with the drug, medicament, vitamin, mineral or controlled dietary matter or content and said acoustics or vibrations being used simultaneously, sequentially or both, or (b) employed, at least in part, to ameliorate the side effects of any acoustic or vibratory exposure itself, or (c) an anti-inflammatory.

36. (currently amended) The apparatus of claim 35 wherein said at least one acoustic or vibratory therapy exposure, directly or indirectly, at least one of enhances, enables, accelerates, initiates or extends the action of said drug, medicament, vitamin, mineral or controlled dietary matter or content in terms of treatment rate or completeness of the extent of treatment benefit.

37. (currently amended) The apparatus of claim 36 wherein said enablement, enhancement, initiation, extension or acceleration is at least one of: (a) caused by the action of

said acoustic or vibratory energy upon said at least one said drug, medicament, vitamin, mineral or ~~ingested~~ controlled dietary matter or content and (b) caused by the action of said acoustic or vibratory energy on the anatomy, body tissue or body fluids of said patient, thereby favorably preparing said anatomy, tissue or body fluid for subsequent and/or simultaneous exposure to said at least one drug, medicament, vitamin, mineral or controlled dietary matter or content.

38. (currently amended) The apparatus of claim 35 wherein said at least one said drug, medicament, vitamin, mineral or controlled ~~diet~~ dietary matter or content provides anti-inflammatory or anti-ischemic benefit.

39. (canceled)

40. (currently amended) The apparatus of claim 35 wherein the acoustic or vibratory exposure of at least some brain or neurological tissues accelerates or enables, directly or indirectly, the perfusion, diffusion, transport, or physical, chemical or biological therapeutic action of said at least one said drug, medicament, vitamin, mineral or controlled ~~ingested~~ dietary matter or content or of a reactive species or product thereof.

41. (currently amended) The apparatus of claim 35 wherein acoustic streaming, acoustic radiation-pressure or acoustic-cavitation developed in or near said brain or neurological region by said acoustic or vibratory exposure assists in transport, perfusion, diffusion, disbursement, delivery or distribution of said at least said one drug, medicament, vitamin, mineral or controlled dietary ~~ingested~~ matter or content or of a subspecies, constituent or byproduct thereof.

42. (currently amended) The apparatus of claim 35 wherein at least said one drug, medicament, vitamin, mineral or controlled dietary matter or content comprises or includes at least a microbubble or microparticulate agent administered or ingested into the body, into the blood, into a tissue or bodily fluid or into a brain or neurological region, said agent providing for enhanced or reduced power-threshold cavitation or bubble oscillation when under acoustic or vibratory illumination, said enhanced cavitation or oscillation at least micromechanically

and therapeutically contributing to at least one of a plaque breakup, formation-interference, or disease-aiding therapy process.

43. (currently amended) The apparatus of claim 42 wherein said microbubble or microparticulate also acts as a ~~drug or medicament~~ substance carrier or ~~drug~~substance-bearing medium, at least one therapeutic ~~drug or medicament~~ substance emanating from said microbubbles or microparticles at some point after administration or ingestion into the body of said patient, said emanation taking place by natural leakage, diffusion or release of ~~drug~~ said substance from said microparticles or by acoustically excited release, diffusion or leakage from said particulates.

44. (currently amended) The apparatus of claim 35 wherein at least one said drug, medicament, vitamin, mineral or controlled dietary matter or content supporting the therapy, directly or indirectly, includes at least one of: 4-hydroxynonenal, acetylcholinesterase or acetylcholine modulators, 1-amino-3,5-dimethyladamantane hydrochloride, acetyl-1-carnitine, alpha 2-macroglobulin drugs, alpha-synuclein or synuclein modifiers or modulators, antibodies, anti-coagulants, anti-inflammatories, anti-ischemics, anti-oxidants, anti-sense drugs, apolipoprotein or apolipoprotein-gene modifiers or modulators, apomorphine-based molecules, donepezil, aspirin, beta-secretase modifiers or modulators, biological reducing agents, celecoxib, 5-aminosalicyclic acid, chelation modulators or agents, cholesterol modulators, cholinergic drugs, coenzyme Q10, tacrine-hydrochloride, cognition-enhancing drugs, cyclooxygenase-2 (COX-2) inhibitors, C-terminal tau inhibitors, diets controlling calories or fat, diets providing anti-oxidants, diets providing vitamins or minerals, domain ligands, donepezil, diazespam, drugs which affect protein kinase C pathways or tyrosine kinase pathways or phosphotyrosine pathways, drugs which affect copper or zinc binding to clioquinol, drugs which modulate aluminum, zinc, copper, iron, fluoride or calcium species, estrogen, drugs which affect APP protein or mutant APP, drugs which affect any one of APOE or APOEe4 or any APOE allele, drugs which affect presenilin protein or presenilin 1, drugs which affect a proteolysis function, drugs which affect tau genes or tau mutations, drugs which affect the behavior of chromosome 17, drugs which reduce oxidative damage, drugs which reduce oxidative damage to RNA, drugs which reduce free radicals, estrogen-like drugs or estrogen-like replacement therapies (ERTs), drugs which treat the cholinergic system, rivastigmine tartrate,

folate or folic acid modulators, galantamine, gamma-secretase drugs, gene delivery drugs, genetically engineered drugs, Ginkgo Biloba, glutamate modulators, homocysteine modulators, hormones, Hydrochloride, hyperzine A, H_2O_2 modulators, ibuprofen, immunomodulating drugs, indomethacin, inflammatory cytokines, insulin degrading enzyme IDE, iron modulators or modifiers, ketone drugs, kinesin-1 modulators, leteprinim potassium, lithium, M-CSF or macrophage colony stimulating factor, memantine, mimetics, monoclonal antibodies, matrix metalloproteinase (MMP) modulators, leteprinim-potassium, neurotrophic factors, neural growth factors (NGFs), notch protein drugs, non-steroidal anti-inflammatories (NSAIDS), nitric oxide modulators, parkin gene modulators or modifiers, peptides, plasmins, PP1 enzyme blockers, prednisone, prodrugs, protease inhibitor gene drugs, protein-kinases, proteolytic antibodies, R-flurbiprofen, galantamine HBr, rivastigmine, serum nerve growth factor, rofecoxib, statins, stem-cells or stem-cell derived medicaments, steroids, tacrine, transplanted cells, transplanted cell constituents, transplanted genetic materials, transplanted body fluids or fluid constituents, triterpenoids, ubiquitin-C-hydrolase-L1, vaccines, rofecoxib, vitamins, Vitamin C, and Vitamin E, beta-amyloid modifiers or modulators, tau modifiers or modulators, vaccines, PYM50228, gamma-aminobutyric acid (GABA), GABA-like drugs, muscimol, benzodiazepines, Wnt, beta-catenin, HoxB4, and talsaclidine.

45. (currently amended) The apparatus of claim 35 wherein the patient at least one of is administered, ingests or takes a said drug, medicament, vitamin, mineral or controlled dietary matter or content before, during or after at least one acoustic or vibratory exposure, the drug, ~~or~~ medicament, vitamin, mineral, or controlled dietary matter or content reaching a tissue to be treated, directly or indirectly, before, during or after an exposure to said acoustic or vibratory energy.

46. (currently amended) The apparatus of claim 1 wherein at least one said substance comprises a drug, medicament, vitamin, mineral or controlled dietary matter or content that is used for at least one of: (a) to provide, enable, initiate, extend or accelerate at least one plaque, protein or prion breakup process, formation-interference process, or disease recovery process and (b) to ameliorate a side-effect of said acoustic or vibratory exposure, and said at least one drug, medicament, vitamin, mineral or controlled dietary matter or content is admin-

istered, ingested, taken-in, therapeutically delivered, provided, prescribed or recommended to said patient.

47. (original) The apparatus of claim 46 wherein said administration or intake is via (a) oral ingestion by eating or drinking, (b) nasal or oral inhalation, (c) injection or introduction anywhere into the body of said patient, either percutaneously, transdermally or via a natural orifice (d) metered or controlled release from outside or inside the body of said patient, (e) via a skin-patch, (f) via a catheter or port, or (g) via the delivery of genetic or cellular materials from outside the body.

48. (original) The apparatus of claim 46 wherein said administration, provision or intake is via metering or controlled release from a pump, injector or other flow, flow-direction, or pressure-controlled source located anywhere outside or inside the body of said patient.

49. (canceled)

50. (original) The apparatus of claim 1 wherein at least one said acoustic or vibratory exposure is arranged or chosen to utilize at least one acoustic or vibratory wavelength which bears a calculatable or histological relationship to a characteristic dimension of a plaque, fibril or prion-related deposit or defect, said choosing causing a desirable mechanical interaction between said plaque, fibril, nodule or defect and said acoustic or vibratory waves, thereby micromechanically contributing to at least one of said breakup, interference, and aiding processes.

51. (original) The apparatus of claim 50 wherein said characteristic dimension is approximately that of a representative plaque, prion, protein, fibril, nodule, defect or deposit dimension.

52. (currently amended) The apparatus of claim 1 wherein a cooling or heat-exchanger ~~means~~ is provided which is in thermal communication with at least one of: (a) an emitter, (b) any of the anatomy of said patient, and (c) the skull of said patient, and heat flows directly or

indirectly either to or from said cooling or heat-exchanger ~~means~~ to or from at least one of an emitter, a patient's anatomy or a patient's skull.

53. (currently amended) The apparatus of claim 52 wherein the cooling or heat-exchanger ~~means~~ provides for: (a) controlling or limiting the temperature of said at least one emitter, directly or indirectly, (b) controlling or limiting the temperature of at least a portion of said patient's anatomy or of the skull of said patient, directly or indirectly, or (c) the use of higher acoustic powers than would otherwise be possible without use of said cooling or heat-exchanger ~~means~~, while maintaining safe maximum patient temperatures.

54. (currently amended) The apparatus of claim 1 further including at least one of: (a) a cooling or heat-exchanger ~~means~~ for transferring heat to or from at least one emitter, from a portion of the patient's anatomy, or from the skull of said patient and the operation of an included cooling or heat-exchanger ~~means~~ is in response or in support of the operation of at least one emitter or to temperatures caused thereby in the skull or anatomy, and (b) said substance ~~a drug, medicament, vitamin, or mineral~~ ~~delivery means providing~~ being delivered to provide a drug, medicament, vitamin, ~~or~~ mineral or controlled dietary matter or content in support of at least one plaque, protein or prion breakup process, formation-interference process, or disease therapy processes, said drug, medicament, vitamin or mineral delivered to said patient responsive to at least one of a flow control, a pressure control, a dosage control, a blood-concentration control, a sensor, a software or firmware program, a system control setting, a sensor, a timer, a real-time or individual-use lab-test or test-sampling, and a practitioner's direction.

55. (currently amended) The apparatus of claim 1 wherein an output of said at least one ~~emitter's output~~ emitter is mechanically scanned relative to said patient's brain, either by patient movement, system movement, emitter movement or emitter relocation on the headgear or a combination thereof.

56. (currently amended) The apparatus of claim 1 further including a removable helmet, head-band or other juxtaposed or head-attached structure for securement to or juxtaposition to the head of said patient, said helmet or structure incorporating or providing a mount-

ing, locating or positioning ~~means~~ device for at least one said emitter, said helmet/structure or emitter(s) therein or thereon becoming acoustically coupled to the patient, said coupling being achieved into or through the patient's scalp or skull thereby allowing delivery of acoustics into the patient.

57. (canceled)

58. (currently amended) The apparatus of claim 56 wherein the ~~patient's head is in a~~ helmet, head-band or head-attachment structure ~~containing or having attached thereto or thereon at least one emitter, said structure having~~ has one or more of an umbilical, cable or coolant lumen which connects or is connectable to said system.

59. (currently amended) The apparatus of claim 1 further including an acoustic ~~coupling means~~ coupler for coupling output from said at least one emitter directly or indirectly into a tissue or body fluid of said brain or neurological system, said acoustic ~~coupling means~~ coupler utilizing at least one of (a) an interposed liquid, gel, paste, cream, emulsion or acoustic-standoff, (b) an interposed inflatable fillable or soakable bag, membrane or sponge material, (c) an interposed acoustically water-like material.

60. (currently amended) The apparatus of claim 59 wherein said acoustic ~~coupling means~~ coupler also provides some skull size or shape adaptability for various-sized or shaped patient's heads for a given patient or from patient to patient.

61. (original) The apparatus of claim 1 wherein operational set-up or compensation is made for at least one of the following variables or changes: (a) variable skull thickness or shape from location to location on a given skull, or variable skull thickness or shape from patient-to-patient, (b) a variable skull, scalp or emitter temperature from location to location or at a single location over time, (c) a change in a relevant or representative brain or neurological temperature, (d) a change in a local or a nearby temperature in a general region of diseased or treated brain or neurological tissue, (e) a change in the result of an invasive or noninvasive lab-test monitoring a variable related to a state of the disease or to a state of a plaque-burden, (f) a change in a metabolic or physiological instrument reading or patient-monitor, (g) a

change in the patient's comfort level, (h) a change or variation in the acoustic velocity, attenuation or dimension of a patient's skull, skin, brain or neurological tissue or plaque, (i) a change or variation in detected brain-tissue perfusion or in cerebral lumen blood-flow, (j) a change in the cavitation or oscillation behavior of a microbubble or microparticulate, (k) a change in an actual or desired concentration or of a delivery parameter of a drug, (l) a change in an actual or desired acoustic power to be delivered, (m) a change in the actual or desired concentration of a species of interest in a blood, urine, skin or spinal fluid test or ongoing sampling, and (n) a change in a brain radiological or functional image or graphical representation, (o) a change in the amount of, nature of or presence of undesired side-effects being experienced or detected or anticipated, (p) a change in blood pressure or cerebrospinal fluid pressure, (q) a change in a state of inflammation whether due to the disease or the acoustics themselves, (r) a change in any brain function, (s) changes in locations or concentrations of plaque, fibrils or nodules within a single patient over time or from patient to patient, and (t) direction provided by software, firmware or by an operator or overseer of the system, regardless of whether any one of these is locally or remotely located.

62. (original) The apparatus of claim 1 wherein acoustic or vibratory energy is also utilized to diagnostically probe or measure a characteristic of the brain, skull, neurological system, disease state, physiology or temperature of said patient or operation of an emitter, the characteristic useful to set up, control or insure safe or efficient operation of said system.

63. (currently amended) The apparatus of claim 1 wherein said at least one ~~acoustic or vibratory~~ emitter comprises an ultrasonic, acoustic or vibratory element which is electrically, electrostatically, magnetically, magnetostrictively, electromagnetically or optically driven or wherein said emitter is an acoustic output port coupled to an acoustic waveguide.

64. (currently amended) The apparatus of claim 1 wherein said at least one ~~acoustic or vibration~~ emitter is coupled, directly or indirectly, into said patient's brain or neurological system through at least one of an upper or lower jaw, neck or spine of said patient.

65. (currently amended) The apparatus of claim 1 wherein said ~~acoustic or vibratory coupling means includes~~ at least one emitter is coupled into a region of said patient's brain or spine by any of:

~~(a) a shaved head or a head with reduced hair quantity;~~

~~(b) wetted hair using any hair-wetting material or a wetted scalp using any scalp-wetting material;~~

(~~e~~a) wetted or gel-coated emitter or emitter portions;

(~~d~~b) inflated or filled expandable acoustically-conductive bags, membranes or standoffs;

(~~e~~c) provision of a saturatable or soakable material which acts as an acoustically transparent standoff or coupler in the soaked state;

(~~f~~d) provision of a flexible or stretchable acoustically-transparent skullcap which is wettable or which promotes acoustically coupling on at least one inner or outer surface;

(~~g~~e) provision of a flexible or stretchable skullcap which serves to control the patient's hair;

(~~h~~f) flow or placement of an acoustically conductive liquid in an emitter/skull interface region;

(~~i~~g) flow or placement of an acoustically conductive coolant or other heat transfer media in an emitter/skull interface region; and

(~~j~~h) flow or placement of an acoustically conductive gel or paste in an emitter/skull interface region.

66. (original) The apparatus of claim 1 wherein at least a portion of one plaque, protein or prion containing deposit, nodule or body undergoes at least one of shear, compressional or tensile-distortion or stress or is excited into a vibratory mode by an acoustic or vibratory emission having a wavelength chosen to bear a relationship to a characteristic dimension of at least one said deposit, nodule or body, the distortion, stress or vibratory behavior favorably contributing to at least one of said therapeutic breakup, interference, and aiding process.

67. (original) The apparatus of claim 1 wherein at least one plaque, protein or prion-containing deposit, nodule or body is or are, at least in part, one of spatially distributed, diffusely distributed, aggregated, agglomerated, intracellularly situated, extracellularly situated, fibril-like, plaque-like, have a microscopic sheet structure or are directly or indirectly associated with cognitive losses.

68. (currently amended) The apparatus of claim 1 wherein the acoustic or vibrational excitations in combination with ~~an~~ said optional ~~drug~~ substance comprising a drug, medicament, vitamin, mineral, controlled dietary matter or content to provide a disease-therapy process in order to ultimately achieve at least one of: (a) enhanced perfusion, diffusion, transport or distribution of blood or cerebrospinal fluid or fluid constituents including disease species, (b) enhanced perfusion, diffusion, transport or distribution of ~~a~~ said drug, ~~or~~ medicament, vitamin, mineral, or controlled dietary matter or content, (c) enhanced perfusion, diffusion, transport or distribution of a functional signaling chemical or species, (d) enhanced cognitive function, (e) enhanced transport of a plaque, prion or deposit breakdown product or related debris, (f) enhanced perfusion, diffusion, transport or distribution of a medicament incorporating stem cells, living cells, or byproducts or derivatives of cells, whether natural cells or genetically manipulated cells, and (g) delivery or distribution of dead or living cells or cell constituents or derivatives serving as a vaccine.

69. (currently amended) The apparatus of claim 1 wherein at least one of: (a) said acoustic or vibratory exposure contributes to enhanced cognitive function or a decrease in the rate of cognitive loss, and (b) said acoustic or vibratory exposure combined with the sequential or simultaneous use of ~~a~~ said optional substance comprising a drug, medicament, vitamin, mineral or controlled dietary matter or content ~~intake~~ both contribute in at least some manner to enhanced cognitive function or a decrease in the rate of cognitive loss, regardless of whether said acoustic or vibratory energy provides, enables or accelerates the action of the drug, medicament, vitamin, mineral or controlled dietary content or matter.

70. (currently amended) The apparatus of claim 69 wherein said acoustic or vibratory energy provides, enables, accelerates or initiates a beneficial action of at least one said drug,

medicament, vitamin, mineral or controlled dietary content or matter, either directly or indirectly.

71. (original) The apparatus of claim 1 wherein it causes the concentration or activity of a chemical, genetic, cellular or biological material, reactant, product or byproduct which plays a damaging role or is involved in the damage sequence or chain of events of the neurodegenerative disease to be at least partly reduced, partly inactivated, chemically tied up or rendered inactive such that the rate of neural damage is slowed or stopped.

72. (original) The apparatus of claim 71 wherein said activity or concentration is reduced, tied up or made inactive accompanied by its ultimate removal from the body with the help of a natural body process, possibly acoustically enhanced, including at least one of: (a) brain metabolism, (b) brain perfusion or circulation of blood, (c) cerebrospinal fluid production or circulation, and (d) body excretion as waste.

73. (original) The apparatus of claim 72 wherein said acoustic or vibratory exposure facilitates or accelerates said subsequent removal in any manner.

74. (original) The apparatus of claim 1 wherein the patient at least one of:

(a) receives an initial lab-test, imaging session, diagnostic session or other exam or test in order to stage the disease or to understand the disease potential;

(b) receives a plaque, protein or prion material-breakup, formation-interference or disease-aiding therapy over a period of one or more sessions;

(c) receives a combination of at least two of breakup, interference or aiding therapies over a period of one or more sessions;

(d) receives at least one each of said breakup, interference, and aiding therapy in at least one session;

(e) receives at least one each of said breakup, interference, and aiding therapy over a period of two or more sessions;

(f) has a body fluid or tissue sample taken before, during or after at least one therapy session;

(g) has a body fluid or tissue analyzed or monitored invasively or noninvasively, before, during or after at least one therapy session; and

(h) undergoes functional imaging or cognitive testing.

75. (currently amended) The apparatus of claim 1 wherein cooling or heat-exchange is employed to maintain, limit or control a temperature related to the patient's anatomy or to the ~~therapy~~ delivery ~~means~~ of said acoustic, ultrasonic or vibratory energy, regardless of whether the system is aware of the actual temperature present or temperature being controlled.

76. (original) The apparatus of claim 1 wherein a wired, wireless, digital, analog, telephony, data, fiberoptic, video or network connection allows for interaction with the therapy apparatus or patient from a distance or from a remote location.

77. (currently amended) The apparatus of claim 1 wherein at least one of: (a) multiple emitters are employed, each primarily treating at least some unique emitter-assigned brain or neurological system region or subregion, (b) multiple emitters are employed and there is a significant overlap in the treated or treatable regions or subregions addressable by said emitters, (c) multiple emitters are employed in any manner and operated sequentially, (d) multiple emitters are employed in any manner and operated simultaneously, (e) multiple emitters are employed in any manner and at least two are operated with controlled phase angle delays relative to each other, (f) at least one emitter comprises multiple acoustic subelements, (g) at least one emitter steers or shapes emissions, at least in part, using a mechanically shaped acoustic component, (h) at least one emitter is moved among at least two different possible mountable positions or angles over a period of one or more therapies, (i) at least one emitter mates with electrical or coolant connectors predisposed in the helmet or headgear, (j) at least one emitter structure also serves to form the structure of the helmet itself, (k) the helmet or headgear or emitter housing or holder is, at least in part, directly made from material which is capable of emitting or receiving acoustic energy, (l) the helmet or headgear is mechanically mated to the patient during operation, (m) the patient rests or places his/her head juxtaposed against or to a pillow-like entity which holds an emitter, (n) the headgear, helmet or pillow structure holding at least one emitter also incorporates a thermal controller ~~means~~ during operation, (o) an emitter is chosen for its frequency or penetration ability, (p) an emitter is chosen for its fit to the

helmet or to the patient, (q) the patient sits, reclines or lies down during the therapy, (r) the patient is entertained with audio and/or video content during the therapy, (s) the patient undergoes therapy using a portable or semiportable system, (t) the patient undergoes therapy at home, at a clinic, at a doctor's office, at an outpatient office, at a hospital or at a nursing home, (u) the patient intakes a drug, medicament, controlled dietary content or therapeutic genetic or cellular substance before, during or after at least one therapy session, both the emissions and the drug contributing individually or cooperatively, to therapeutic benefit, (v) comfort or adjustability is provided by an intervening acoustic standoff which is shapable, the emitters passing their emissions through said standoff, the shapability adaptable to the patient's head, (w) a shapable acoustic standoff serves as a conforming pillow for patient comfort or for improved acoustic coupling, (x) a patient acoustic ~~coupling means~~ coupler incorporates a thermal control feature, or (y) an emitter itself incorporates a connector or a thermal controller ~~means~~.

78. (original) The apparatus of claim 1 wherein said acoustic or vibratory exposure is of intensities or powers which allow for prolonged exposure or multiple exposures of said patient's brain or neurological system without accumulating unacceptable acoustically-induced permanent damage to neurologically significant portions of the patient's anatomy, tissues or fluids.

79. (original) The apparatus of claim 1 wherein said acoustic or vibratory exposure is of intensities or powers such that the accumulated time at temperature of treated brain regions is below that which would cause significant permanent thermal damage to healthy cells.

80. (original) The apparatus of claim 1 wherein the ultrasonic or vibratory power per unit area is between 5 milliwatts per square centimeter and 10 watts per square centimeter.

81. (currently amended) The apparatus of claim 80 wherein at least one of:

(a) at least one frequency between 1 hertz and 2 megahertz is employed ~~with or without cooling or heat exchange~~;

(b) at least one frequency of between 2 megahertz and 5 megahertz is employed ~~with cooling or heat exchange~~;

(c) the temperature rise in a portion of the patient's tissue or bodily fluid is limited to 5 degrees centigrade or less;

(d) the duty cycle of the acoustic power is set between 10 and 25% on-time; and

(e) healthy tissues are spared permanent unacceptable thermal or acoustic damage.

82. (currently amended) The apparatus of claim 1 wherein said at least one ~~acoustic~~ emitter is inside the skull of said patient or in an interior location of said patient's brain or neurological system and acoustic or vibratory energy emanates in at least one direction generally outward toward a patient's scalp or toward a skinline.

83. (currently amended) The apparatus of claim [[1]] 17 wherein ~~any emitter energy~~ said beam-forming or beam-steering ~~is done at least for the purpose of achieving~~ provides increased or more uniform coverage of targeted or targetable brain or neurological regions.

84. (original) The apparatus of claim 1 wherein the disease or incipient disease being treated is, at least in part, resident in any of the following brain or neurological tissues: hippocampus, entorhinal cortex, cerebral cortex, posterior cingulated cortex, neocortex, allocortical regions, basal forebrain, or cerebellar tissues.

85. (original) The apparatus of claim 1 wherein at least some of the acoustic or vibratory energy is capable of providing, enabling, accelerating or initiating a plaque, prion or protein containing breakup-process, interference-process or disease-aiding process, the acoustic or vibratory therapy process itself not requiring a drug, medicament or controlled dietary content to proceed at a useful pace or to a useful extent.

86. (original) The apparatus of claim 85 wherein said breakup, interference or aiding process enhances patient cognition at least after some time has passed.

87. (original) The apparatus of claim 1 wherein a drug, medicament or controlled dietary content is used to comfort the patient or to relieve existing or potential side-effects of an acoustic or vibratory exposure, regardless of whether it contributes to the therapy itself

88. (original) The apparatus of claim 1 wherein cognition loss is at least slowed, stopped or reversed at least after some time has passed.

89. (original) The apparatus of claim 1 wherein the primary physical components of said apparatus include a console or control box, a headpiece incorporating at least one said emitter, and at least one connecting or connectable cable or lumen connecting said console and said headpiece.

90. (original) The apparatus of claim 1 wherein a bodily fluid such as blood or cerebrospinal fluid is manipulated in any manner in cooperation with at least one said acoustic or vibratory exposure or by said exposure, the combined exposure and manipulation having at least one of additive, extending or acceleration-of-therapy effects.

91. (currently amended) A method for the therapeutic treatment of abnormal protein-related or prion-related diseases of a human patient's brain or neurological system comprising:

(a) coupling at least one acoustic or vibratory emitter into a patient's brain or neurological system or portion thereof; and

(b) exciting said emitter to emit acoustic or vibrational energy with a desired characteristic directly or indirectly into or through said brain or neurological system or portion thereof, the emitted energy designed to provide, enable, accelerate or initiate at least one of the following therapy processes in cooperation with the optional use of a drug:

(1) physical breakup, breakdown, erosion, dispersion, disentanglement, de-aggregation, redistribution, dissolution, de-agglomeration, de-amalgamation or permeation of at least some disease-related deposits, nodules or bodies thereby improving the transport of a disease species out of the body by at least one of a shunt, a port, a natural bodily process, an energy-enhanced natural bodily process, natural or enhanced bloodflow, or by natural or enhanced CSF flow,

(2) at least temporary opening of the blood-brain-barrier (BBB) or arachnoid-villi for the purpose of enabling or improving the transport of a disease related species out of the body, by ~~any means~~ including an artificial shunt or port ~~means~~ and enhanced arachnoid-villi flow,

(3) acoustic or vibrational stirring or mixing of blood or cerebrospinal fluid for the purpose of enabling or improving the transport of a disease related species out of the body, by ~~any means~~ including an artificial shunt or port ~~means~~ or any natural bodily ~~means~~ mechanism,

(4) enhancing the transport of a disease-related species by enhancing or enabling CSF or bloodflow via acoustic streaming effects or by acoustic exposure causing at least temporary increases in membrane or tissue permeabilities, and

(5) ~~drug~~substance-aided attack upon said deposits, nodules or bodies wherein the acoustic energy at least one of (i) aids in transporting the ~~drug~~ substance (ii) activates the ~~drug~~ substance, (iii) enhances the benefit delivered by the ~~drug~~ substance, (iv) enhances the rate or extent of attack of the ~~drug~~ substance upon said deposits, nodules or bodies, and (v) has accelerated or extended benefit because of the cooperative action of the ~~drug~~ substance, where the substance is at least one of a drug, medicament, vitamin, mineral or controlled dietary matter or content.

92. (currently amended) The method of claim 91 wherein ~~a~~ said drug, medicament, vitamin, mineral or controlled dietary matter or content optionally being administered enhances therapy effectiveness or patient comfort, independently or in cooperation with the emitted energy.

93. (currently amended) The method of Claim 92 wherein ~~a~~ said drug, medicament, vitamin, mineral or controlled dietary matter or content which is administered is at least one of: (a) known to provide useful therapy even without the acoustic emissions present, and (b) requires acoustic emissions to directly or indirectly cause the ~~drug~~ substance to be of therapeutic benefit.

94. (currently amended) The ~~system~~ method of claim 92 wherein ~~an administered~~ said drug, medicament, vitamin, mineral or controlled dietary matter or content has its therapeutic

contribution enabled, enhanced, initiated, accelerated or extended due to an effect, latent effect or side-effect of at least one acoustic exposure.

95. (original) The method of claim 91 wherein the acoustic emissions are unfocused, weakly focused, diffused, diffuse, collimated or overlapping spatially or temporally.

96. (currently amended) The method of claim 91 wherein ~~the drug~~ said substance also serves as an imaging contrast agent or serves to minimize an undesirable side-effect of the acoustic exposure.

97. (currently amended) The ~~system~~ method of claim 91 wherein acoustic measurements or imaging is also practiced in support of the therapy, regardless of whether any of the therapy emitters are also used for said measurements or imaging.

98. (original) The method of claim 91 wherein blood or cerebrospinal fluid is otherwise manipulated in cooperation with the emission therapy, said manipulation comprising at least temporary shunting of blood or cerebrospinal fluid.

99. (original) A method for providing therapy to a patient having, or who may potentially develop, a neurodegenerative disease characterized by abnormal proteins or prions or related deposits comprising:

(a) delivering acoustic, ultrasonic or vibratory energy in, into, through, toward, from within or coupled-into a region of the patient's brain or spine which contains, or is in transportable communication with, cerebrospinal fluid (CSF) or blood capable of bearing or bearing a chemical or biological species, reactant, fragment, by-product or species related to the disease;

(b) the emitter operable to at least one of: (1) enhancing, promoting or enabling, directly or indirectly, the formation and/or transport of the species, reactant, fragment or byproduct which is at least ultimately transportable out of a brain or spine region and into a CSF space, lumen, cavity or bloodstream, (2) enhancing the transport or mixing of the species within CSF and/or blood or across tissues or existing barriers and membranes, and (3) enhancing or promoting the increased production of fresh CSF or blood;

(c) said at least one of enhanced formation, transport, mixing or production contributing at least ultimately to some removal of said species from the body and/or at least some immediate or later reduction in concentration of said species in a portion of the body at least in part by using one or more natural paths, emitter-enhanced paths, drug-enhanced paths, surgical or artificial ~~shunting means~~ shunt, port ~~means~~, or internal or external dialysis ~~or filtering means~~ filter, thereby at least slowing or stopping a disease process; and

(d) said patient optionally receiving a ~~drug~~ substance before, during or after an operation of the emitter(s) to at least one of: (1) act or help act against a disease process or a contributing factor thereto, (2) promote the formation or transport of a species that is to be removed or is more easily removable than a natural species, (3) encourage or enable growth or regrowth of new or transplanted brain or stem cells or enhance functional brain or neural pathways, (4) encourage or enable the beneficial uptake, processing or interaction of a genetic medicament, and (5) minimize potential or expected side-effects of an emitter exposure or shunting or port procedure., at least one such drug acting at least one of independently of, in cooperation with, or synergistically with an acoustic exposure.

100. (currently amended) A method of at least temporarily slowing, stopping or avoiding a patient's cognitive losses associated with a neural deposition disease comprising administration of acoustic or vibrational energy directly or indirectly into affected or potentially affected patient anatomy portions thereby causing at least one of: (i) acoustically or vibrationally enhanced or enabled beneficial transport of a disease-related species into, to, through or out of a CSF or blood transport path, (ii) acoustically or vibrationally enhanced or enabled beneficial transport of a disease-related species into, to, through or out of a ventricle, bodily lumen, bodily organ, shunt, port or artificial fluid ~~extraction means~~ extractor, (iii) acoustically or vibrationally enhanced or enabled beneficial transport of a disease-related species across a blood-brain-barrier (BBB), arachnoid-villi, or across any membrane or tissue, and (iv) acoustically or vibrationally enhanced or enabled beneficial increases in the bodily production of fresh CSF.

101. (currently amended) The method of claim 100 wherein at least one of the following is practiced:

(a) imaging diagnostics in support of at least one said therapy treatment;

(b) performance of a lab or clinical test upon the patient or his/her body or bodily specimens in support of at least one said therapy treatment;

(c) cognitive testing or grading in support of at least one said therapy treatment;

(d) delivery of a ~~drug or medicament~~ substance to the patient in any form, the ~~drug~~ substance acting independently or in cooperation with the acoustic or vibratory therapy;

(e) vascular delivery of an acoustic or energy emitter or energy source:

(1) through-skull or skull borehole delivery of acoustic energy or energy source,

(2) CSF or blood removal, temporary or otherwise, or

(3) CSF or blood filtering or dialysis performed in or outside of the body;

(f) at-home, out-patient, doctors office or clinical delivery of at least one therapy session; and

(g) one or more therapy sessions regardless of how many visits that requires of the patient, if any.

102. (new) The method of claim 99 wherein said substance comprises at least one of a drug, medicament, vitamin, mineral or controlled dietary matter or content.

103. (new) The method of claim 101 wherein said substance comprises at least one of a drug, medicament, vitamin, mineral or controlled dietary matter or content.